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| 09/459,171      | 12/10/1999  | LEO J. ROMANCZYK JR. | 5677-085            | 9742             |

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT PAPER NUMBER

1626

DATE MAILED: 08/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/459,171

Applicant(s)

ROMANCZYK ET AL.

Examiner

Taofiq A. Solola

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 120-224 is/are pending in the application.
- 4a) Of the above claim(s) 120-131, 144-193 and 205-224 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 132-143 and 194-204 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 20 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22. 6) ☐ Other: .

This action supersedes all previous Office Actions.

Claims 120-224 are pending in this application.

Claims 120-131, 144-193, 205-224 are drawn to non-elected inventions.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 120-131, 216-224, drawn to procyanidin composition and method of use as anti-inflammmtory agent, classifiable in class 514.
- II. Claims 132-143, 194-204, drawn to procyanidin composition and methods of use as antiplatelet agent, classifiable in classes 549, 514.
- III. Claims 144-152, drawn to procyanidin composition and methods of use for improving or mitigating vascular health, classifiable in classes 549.
- IV Claims 153-161, drawn to procyanidin composition and methods of use for reducing the risk of thrombosis, treating or preventing arteriosclerosis and restenosis, classifiable in classes 514, 549.
- V Claims 162-170, 205-215, drawn to procyanidin composition and methods of use for improving or mitigating vascular health, classifiable in classes 549.
- VI Claims 171-179, 186-193, drawn to procyanidin composition and methods of use for treating NO-dependent hypertension, classifiable in classes 549.
- VII Claims 180-185, drawn to procyanidin composition in admixture with cyclo-oxygenase inhibitor, classifiable in classes 514.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I -VII, are related as product and methods of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the methods for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different methods of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in materially different methods of using the product as in groups I-VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Nada Jain on 7/19/02 a provisional election was made without traverse to prosecute the invention of group II, claims 132-143, 194-204. Affirmation of this election must be made by applicant in replying to this Office action. Claims 120-131, 144-193, 205-288 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant did not indicate if election of group II, claims 132-143, 194-204, is made with or without traverse. Therefore, the election is deemed made without traverse.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 141-143, 202-204 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The subject matter of the claims are not disclose in the specification as originally filed. For example, there is no support for the terms "aspirin" or cyclo-oxygenase modulator." Therefore, claims 141-143 constitute new matter and must be withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 197-198 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 197-198 are improperly dependent on claim 194, and therefore are indefinite. The claims are drawn to compositions while claim 194 is drawn to a method of use.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 132-140, 197-198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clapperton et al., "Polyphenols and Cocoa Flavour", presented at the XVIth Internat. Conference of the Groupe Polyphenols, Lisbon, Portugal, vol. 16, 1992.

Applicants claim composition comprising polyphenol (procyanidin) from cocoa. In preferred embodiment the procyanidin is in dimer or oligomer, which may have 4-6 and/or 4-8 linkages. The compositions are in packages having instruction on methods of use.

#### **Determination of the scope and content of the prior art (MPEP §2141.01)**

Clapperton et al., disclose composition comprising polyphenol (procyanidin) from cocoa. See the summary, page 1, paragraph 2. The procyanidins are in monomers and oligomers (table 1). The compositions are made into liquor (page 2, paragraph 4, line 2).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Clapperton et al. is that applicants claim composition in packages having instruction on methods of use. Also, Clapperton et al., do not teach the type of linkages in the dimmer and/or oligomers.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

However, being in packages having instruction on methods of use is not patentable significant. Having composition in packages with instruction on methods of use is well known in the art. Also, it is well known in the art that the linkages commonly formed by dimmer and/or oligomers of procyanidins are 4-6 and/or 4-8. For example, see US 4,797,421 (cols. 2-7) and Chang et al., Prostag. Leuk. Essent, Fatty Acids (1989), Vol. 38, pages 181-188. Applicants also failed to provide evidence that the linkages in the dimmer and/or oligomers of Clapperton et al., are not 4-6 and/or 4-8. Therefore, the instant invention is prima facie obvious from the teaching of Clapperton et al. One of ordinary skill in the art would have known to package the composition of Clapperton et al., with instruction on methods of use at the time the invention was made. The motivation is to make additional composition comprising polyphenol (procyanidin).

Claims 194-196, 199-201 rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al., Prostag. Leuk. Essent, Fatty Acids (1989), Vol. 38, pages 181-188, in view of Clapperton et al., "Polyphenols and Cocoa Flavour", presented at the XVth Internat. Conference of the Groupe Polyphenols, Lisbon, Portugal, vol. 16, 1992.

Applicants claim a method of antiplatelet therapy comprising the use of oligomer of procyanidins, wherein the oligomer has 4-6 and/or 4-8 linkages. And is obtained from cocoa.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Chang et al., teach a method of antiplatelet therapy comprising the use of dimmers and oligomers of procyanidins, wherein the dimmers and oligomers have 4-6 and/or 4-8 linkages. See column 2, page 182.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant invention and that of Chang et al., is that applicants are claiming procyanidins from cocoa instead of plants by Chang et al.

*Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)*

However, the term "plants" embraces "cocoa," and Clapperton et al., teach procyanidin dimmers and oligomers are obtained from cocoa. Also, no matter how or where obtained the procyanidins oligomers are the same. Therefore, the instant invention is prima facie obvious from the teachings of Chang et al., and Clapperton et al. One of ordinary skill in the art would have known to extract procyanidins from cocoa at the time the invention was made. The motivation is to make additional compounds useful for antiplatelet therapy.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703)



308-4690. The examiner is on flexible work schedule and is generally out of the office on Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Taofiq A. Solola', written over a horizontal line.

Taofiq A. Solola, Ph.D.

Primary Examiner

Group 1626

August 19, 2002